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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/577,268	12/18/2006	Tove Ringerike	76222-PCT-US/GJG	2090

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EXAMINER	
HIBBERT, CATHERINE S	

ART UNIT	PAPER NUMBER
1636	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/577,268	RINGERIKE ET AL.	
	Examiner	Art Unit	
	CATHERINE HIBBERT	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 December 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *4,8,9,11-13,15,16,24 and 44-52* is/are pending in the application.

4a) Of the above claim(s) *24* is/are withdrawn from consideration.

5)☒ Claim(s) *8 and 45-51* is/are allowed.

6)☒ Claim(s) *4,9,11-13,15,16,44 and 52* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicants' Amendments to the Specification filed 9 December 2010 is received and entered. This US Application 10/577,268 filed 26 April 2006, is a 371 National Stage entry of PCT/PL2004/000075, filed 26 September 2004, which claims foreign priority to PCT/PL2003/00098, filed 26 September 2003. Claims 1-3, 5-7, 10, 14, 17-23 and 25-43 are cancelled. Claim 24 is are withdrawn. Claims 4, 8-9, 11-13, 15-16, 24 and 44-52 are pending. Claims 4, 8-9, 11-13, 15-16 and 44-52 are under examination. This action is Non-Final in view of new grounds of rejection.

Election/Restrictions

Claims 8 and 46 are directed to an allowable product. Pursuant to the procedures set forth in MPEP § 821.04(B), claim 52, directed to the process of making or using an allowable product, previously withdrawn from consideration as a result of a restriction requirement, is hereby rejoined and fully examined for patentability under 37 CFR 1.104.

Response to Amendments/Arguments

The objection to the specification is withdrawn based on Amendments to the Specification filed 9 December 2010.

The rejection of claims 9, 11-13, 15-16 and 46-51 under 35 U.S.C. 101 is withdrawn in view of Applicant's statement on page 8 of Applicant's Remarks filed 9 December 2010 to disavow any interpretation of the term "single-celled host" which would read on a cell present in a human being.

The rejection of claims 9, 11-13, 15-16 and 46-51 under 35 U.S.C. § 112, first paragraph, is withdrawn based on Amendments to the Specification filed 9 December 2010.

New grounds of rejection

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 4, 9, 11-13, 15-16 and 44 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 4, 9, 11-13, 15-16 and 44 are indefinite because claims are drawn to an isolated nucleic acid molecule "coding an expression box" with a specified formula, wherein the expression box is "contained in" a specified plasmid. Thus, it is unclear whether the isolated nucleic acid molecule of claim 4 *requires* any one of the plasmids listed in claim 4 as SEQ ID NO's 1-35 or whether the claim is reciting the plasmids listed in claim 4 as SEQ ID NO's 1-35 in order to *define* the required expression box present in the isolated nucleic acid and therefore the metes and bounds of the claim cannot be determined to one of ordinary skill is the art.

Additionally, claim 9 recites the limitation "a DNA molecule according to claim 4" in line 2. There is insufficient antecedent basis for this limitation in the claim because the base claim 4 does not explicitly recite the term "a DNA molecule" and it is unclear if the antecedent basis is intended to be drawn to any one of the plasmids listed in claim 4

as SEQ ID NO's 1-35 or whether "a DNA molecule" could encompass the various nucleic acid sequences listed in the claim, such as "a promoter sequence" or an expression box sequence.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 52 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a screening assay using the single-celled host according to claim 46 using the test substances such as those described in Table II or in Figure 20 of the instant specification, using the defined reporter gene assays described in the instant specification, does not reasonably provide enablement for a screening assay using any test substance and any reporter gene assay to conclude that a change in the level of expression described in step (b) is accepted as a characteristic of the tested substance. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The test of enablement is whether one skilled in the art could make and use the claimed invention from the disclosures in the application coupled with information known in the art without undue experimentation (*United States v. Telectronics, Inc.*, 8 USPQ2d 1217 (Fed. Cir. 1988). Whether undue experimentation is required is not based upon a single factor, but rather is a conclusion reached by weighing many factors. These

factors were outlined in *Ex parte Forman*, 230 USPQ 546 (Bd. Pat. App. & Inter. 1986) and again in *In re Wands*, 8 USPQ2d 1400 (Fed. Cir. 1988) and include the following:

1) Unpredictability of the art. The art in the area of screening assays using mammalian and human cell lines for any type of test substance, any type of reporter assay with undefined parameters for is unpredictable. The research required to determine significant expression results to indicate an "accepted characteristic" of a test substance involves complex test parameters and controls. It is difficult or impossible to *a priori* predict that any change in expression level of any reporter gene in the claimed single-celled host cells would be indicative of an accepted characteristic of the tested substance. Indeed, even the verification of a known property using pre-selected chemical test substances showing appropriate EC50 values in various human immortal cell lines is an endeavor which requires extensive inventive research. Examples of the type of research required to identify a characteristic of a tested substance are exemplified by Glimcher et al in "Compositions and Methods for the Treatment and Prevention of Ulcerative Colitis And Colon Cancer And Screening Methods to Identify Same (US Patent 7,393,944, filed 3 December 2001, whole document, of record).

2) State of the art. The art with regard to characterization of tested substances using mammalian and human cell lines and undefined assay parameters must be considered to be poorly developed.

3) Amount of guidance provided by applicants; and 4) Number of working examples. With the exception of the example provided in Figure 22, showing expression of IL-1-beta and GFP using macrophages J774A.a and J.1.5.4 cells

stimulated with the test substance tetrachloroplatinate TCP (and selected chemicals from the list of model immunotoxicants having EC50 values showing concentration causing death of 50% of cells in the populations, obtained with MTT assay, applicants present no working examples of the claimed invention using *any* non-selected test substance, any reporter assay and any undefined expression parameters to determine an accepted characteristic of the tested substance.

5) Scope of the claims. The claimed invention is extremely broad in scope. The invention reads on any change in the level of expression of any reporter gene following contact by any test substance with the claimed single-celled hosts as an accepted characteristic of the tested substance. The claim does not include controls or set parameters for the type of levels of expression being measured.

6) Nature of the invention. The invention involves complex, unpredictable, aspects of any "test" substance contacted to cell lines, including immortal human cell lines to provide an "accepted characteristic" of the test substance.

7) Level of skill in the art. The level of skill in the art is high; however, given the complex, unpredictable aspects of the invention, the lack of guidance presented by applicants, the lack of working examples and the broad scope of the invention, it must be considered that the skilled artisan would have had to have conducted undue and excessive experimentation in order to practice the claimed invention.

Given the analysis of the factors which the courts have determined are critical in determining whether a claimed invention is enabled, it must be considered that the skilled artisan would have had to have practiced essentially trial and error

experimentation in order to try to practice the claimed invention. Said experimentation must be considered to be undue and excessive.

Conclusion

Claims 8 and 45-51 are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CATHERINE HIBBERT whose telephone number is (571)270-3053. The examiner can normally be reached on M-F 8AM-5PM, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joanne Hama can be reached on 571-272-2911. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/NANCY VOGEL/
Primary Examiner, Art Unit 1636

Catherine S. Hibbert

Examiner AU1636